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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,687	02/14/2001	Laurent Benbadis	33339/206076	8151

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,687

Applicant(s)

BENBADIS ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 11-18 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 08062004.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

Applicant's amendment and response filed August 20, 2003 has been received and entered into the case. Claims 1 – 18 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1651

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 – 2 and 4 – 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hottinger in view of Mainzer.

Applicant claims a strain of *Lactobacillus bulgaricus* (*L. bulgaricus*), lacking beta-galactosidase activity wherein a nonsense mutation occurs in at least one coding sequence of the lactose operon. The coding sequence encodes beta-galactosidase. Applicant further claims a lactic ferment comprising at least one strain of *L. bulgaricus*; and a ferment further combined with *Streptococcus thermophilus* (*S. thermophilus*). Applicant also claims a method for preparing a fermented dairy product comprising fermenting milk using a lactic ferment of the *L. bulgaricus* strain in the presence of at least one sugar, specifically glucose, and arrest of fermentation occurs in a cooling of the product. Finally applicant claims the fermented dairy product obtained thereby, wherein the dairy product is yogurt.

Hottinger teaches a method of preparing yogurt wherein fermenting milk is inoculated with *S. thermophilus* and a lac- mutant strain of *L. bulgaricus*, wherein the *L. bulgaricus* has a deletion of at least part of the beta-galactosidase gene (abstract). Hottinger further teaches the *L. bulgaricus* mutant is incapable of fermenting lactose (or lacks beta-galactosidase activity) (col.3 line 9-11) and that glucose is added to the culture in order to modulated the acidification rate and post-acidification in storage (col.3 line 14-16). Hottinger discloses a known production of yogurt wherein *S. thermophilus* is combined with a strain of *L. bulgaricus* selected for its

Art Unit: 1651

inability to ferment lactose (or lacking beta-galactosidase activity) wherein the starting milk must be supplemented with glucose (col.1 line 43-49).

Hottinger does not teach the method wherein fermentation is arrested without cooling the product. However, one of ordinary skill in the art would have been motivated to do so because Mainzer teaches mutant *L. bulgaricus* organisms which are sensitive to (or decrease in activity or fermentation) conditions (abstract) such as pH (col.2 line 38-42). Mainzer suggests that the pH sensitive strains used in the manufacture of fermented products (e.g. yogurt, col.1 line 40-44) arrests fermentation at certain pH levels, and is an alternative to refrigeration (or cooling) for decreasing the rate of acid formation (col.2 line 38-42). At the time of the invention, one of ordinary skill in the art would have been motivated by Mainzer to arrest the fermentation of Hottinger without cooling, with reasonable expectation for successfully preparing a fermented dairy product.

Hottinger does not teach the *L. bulgaricus* is a non-sense mutant. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to mutate the lactose operon by any known method because it was well known in the art that such mutations yield *L. bulgaricus* strains with desired characteristics. As evidenced by Hottinger, mutations in the beta-galactosidase gene yields strains with a low capacity for acidification and the ability to moderate these properties with glucose. Moreover, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to practice the methods of Hottinger with any method of mutation as a matter of routine practice. In addition, while a point mutation may be different from a deletion mutation, the claimed strain appears to demonstrate properties described by Hottinger. Namely, a low acidification rate with the

Art Unit: 1651

capability of being moderated by glucose. At the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to practice the methods of Hottinger with a non-sense strain. Furthermore, since the non-sense mutation of the claimed invention is always devoid of beta-galactosidase activity, one in the art would expect the properties to be similar to strains with deletion mutations. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated to practice the method of Hottinger with a non-sense mutated strain with a reasonable expectation for obtaining a mutant with properties described by Hottinger.

Response to Arguments

Applicant argues that it would not have been obvious to one in the art to make a mutant *L. bulgaricus* with a nonsense mutation, that the references do not teach or suggest such a change, and that deletions are not mutations and are thus structurally different.

However, these arguments fail to persuade because Hottinger specifically teaches that mutations in the beta-galactosidase gene yield strains with a low capacity for acidification and the ability to be moderate these properties with glucose. Moreover, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to practice the methods of Hottinger with any method of mutation as a matter of routine practice. In addition, while a point mutation may be different from a deletion mutation, the claimed strain appears to demonstrate properties described by Hottinger. Namely, a low acidification rate with the capability of being moderated by glucose. Furthermore, since the non-sense mutation of the claimed invention is always devoid of beta-galactosidase activity, one in the art would expect the

Art Unit: 1651

properties to be similar to strains with deletion mutations. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated to practice the method of Hottinger with a non-sense mutated strain with a reasonable expectation for obtaining a mutant with properties described by Hottinger. Therefore the claims stand rejected for these and the reasons stated above.

Allowable Subject Matter

In an interview with Raymond Linker on July 19, 2004, claims 1 and 11 – 18 were indicated as allowable subject matter. However, an agreement to cancel non allowable claims was not reached.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1651

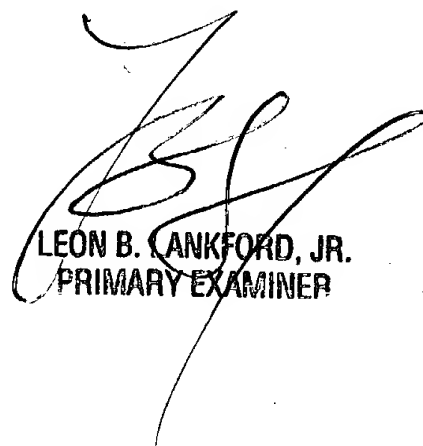
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
August 6, 2004



LEON B. CANKFORD, JR.
PRIMARY EXAMINER